Kalila Medical

APR 0 1 2014

Section 5 510(k) Summary

510(k) Number	K140420	
Submitter Name and Address		
Name:	Kalila Medical	
Contact:	Carrie Neuberger	
Address:	745 Camden Avenue, Suite A Campbell, CA 95008	
Telephone:	415-640-3377	
Fax:	408-903-4095	
Date Prepared:	February 7, 2014	
General Device Information		
Product Name:	Vado Steerable Sheath	
Common Name:	Steerable catheter introducer	
Classification:	21 CFR 870.1340 A catheter introducer is a sheath used to facilitate placing a catheter through the skin into á vein or artery.	
Device Class:	Class II	
Product Code:	DYB	
Predicate Device		
Manufacturer	Device Name	510(k) Number
St. Jude Medical	Agilis NxT Steerable Introducer	K061363
Device Description		
The Kalila Vado Steerable Sheath consists of an 8.8F (ID) sheath and dilator, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer includes a hemostasis valve to minimize blood loss during catheter exchange. A sideport with three-way stopcock is provided for aspiration, fluid infusion, blood sampling and pressure monitoring. A handle equipped with a deflection knob, deflects the tip 140°. The steerable introducer features distal vent holes for aspiration and radiopaque markers to facilitate visualization under fluoroscopy.		
Intended Use (Indications)		
The Vado Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.		
Comparison to the Predicate Device		
The Vado Steerable Sheath has the same intended use and fundamental scientific technology as the predicate device, including biocompatibility, packaging, sterilization, and labeling. Where dimensional differences exist between the subject device and the predicate device, performance testing demonstrates that these differences do not adversely affect safety and effectiveness.		

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This submission supports the position that the Vado Steerable Sheath is substantially equivalent to the St. Jude Medical Agilis NxT Steerable Introducer (K061363).

Summary of Non-Clinical and Clinical Testing

The 510(k) notice contains summaries of biocompatibility and *in vitro* studies conducted to evaluate the performance characteristics of the Vado Steerable Sheath. The data presented demonstrate that the Vado Steerable Sheath met its functional and performance characteristics in accordance with applicable industry standards and compares favorably to the predicate device.

To verify that the Vado Steerable Sheath met its functional and performance requirements, representative sterilized samples of the device underwent sterilization, biocompatibility, bench testing, packaging integrity, and shelf life testing.

Biocompatibility Tests:

1. Cytotoxicity
2. Acute Systemic Toxicity
3. Hemocompatibility (Direct and Indirect)
4. Thrombosis
5. Sensitization
6. Irritation / Intracutaneous
7. Complement Activation
8. Pyrogenicity (rabbit pyrogen and bacterial endotoxin (LAL)

Bench Tests:

1. Steerable Sheath and Dilator Visual Inspection
2. Steerable Sheath Dimension Inspection
3. Steerable Sheath Marker Band Location Measurement
4. Dilator Dimensional Inspection
5. Valve Leakage Resistance at 40kPa
6. Leakage Resistance at 300kPa
7. Device Preparation
8. Dilator Snap Disengagement Force
9. Dilator Insertion and Retraction Force
10. Shaft Deflection
11. Curvature Dimensions
12. Aspiration
13. Catheter Insertion Cycling and Flexion Cycling, with Flush
14. Bend Radius to Kink
15. Corrosion Resistance
16. Junction Strengths
17. Torque and Turns to Failure
18. Steerable Sheath Radiopacity Study

Packaging Integrity Tests:

1. Pouch Seal Strength 2. Gross Leak Detection Pre-Clinical testing is not provided in this submission. Clinical testing is not provided in this submission. The fundamental scientific technology and technological characteristics of the Vado Steerable Sheath are the same as the predicate device including mechanism of action, packaging, biocompatibility, sterilization, and labeling. Through bench performance testing it was demonstrated that the Vado Steerable Sheath does not raise any new questions of safety and effectiveness.
Statement of Equivalence
The Vado Steerable Sheath has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and the predicate device have been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 1, 2014

Kalila Medical, Inc.
C/O Carrie Neuberger
745 Camden Ave, Suite A
Campbell, CA 95008 US

Re: K140420
Trade/Device Name: Vado Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 9, 2014
Received: February 18, 2014

Dear Ms. Neuberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kalila Medical

Indications for Use

510(k) Number (if known): K140420

Device Name: Kalila Medical Vado Steerable Sheath

The Vado Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Kenneth J. Cavanaugh -S